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EXAMINER	
MIDKIFF, ANASTASIA	

ART UNIT	PAPER NUMBER
2882	

DATE MAILED: 12/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/848,812	YEO ET AL.	
	Examiner	Art Unit	
	Anastasia Midkiff	2882	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 May 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25* is/are rejected.

7)☒ Claim(s) *8 and 19* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *18 August 2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

Claims 8 and 19 are objected to because of the following informalities:

Line 8, Claim 8, and Line 13, Claim 19, include the word "film," wherein the placement, or intended use, of said film is not clearly stated. Examiner suggests applicant add sufficient detail to explain where film belongs within apparatus and method for its use.

Claim 19 is further objected to because of the following informalities:

With respect to Claim 19, Line 18 on Page 27 describes "computationally delivering" radiation beams on phantom, wherein the phrase "computationally delivering" is not commonly recognizable in the art. Examiner assumes that applicant is referring to a simulation of radiation that is delivered to patient according to treatment plan and requests that applicant reword the Claim to clarify what is meant by "computationally delivering."

In addition, there is no period at the end of Claim 19, which is required.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to Claim 22, line 22 of page 28, the limiting meaning of "verified beam" cannot be ascertained and, therefore, is indefinite. For examination purposes, this limitation has not been afforded any patentable weight.

Claim 23 is rejected based on its dependency upon Claim 22.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 13-15 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent Application Publication to Moore et al. (PGPUB# 2002/0122535).

With respect to Claim 13, Moore et al. teach a phantom imaging assembly wherein said assembly comprises a fluorescent layer containing a high atomic-number powder of calcium tungstate niobium ($CaWO_4$) (Paragraph 94, Lines 8-15), and a tissue-equivalent plastic compound (Paragraph 134).

With respect to Claim 14, Moore et al. further teach said high atomic number compound comprises at least one element from Group VI of The Periodic Table of Elements, said element being tungsten (W) (Paragraph 94, Lines 8-15).

With respect to Claim 15, Moore et al. further teach said high atomic number powder comprises at least one element from the group consisting of lead and tungsten, said element being tungsten (Paragraph 94, Lines 8-15).

Claim 25 is rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent to Dawson (USP# 6,364,529).

With respect to Claim 25, Dawson teaches a method of exposing film in an x-ray machine (Column 1 Lines 60-67, and Column 2 Lines 1-6), comprising the steps of inserting film between layers of virtual water, tissue-mimicking material (32) to form a sandwich (Figure 1, Column 3 Lines 3-5, and Column 4 Lines 60-62), placing said sandwich in a holding device comprising a chamber (24, 28, and 12), a compression mechanism (36), and legs (16), wherein said legs have a height adjusting mechanism (20), inserting said holding device into an x-ray machine (Column 4, Lines 20-22), adjusting the height of said holding device via height adjusting mechanism (Column 2, Lines 53-56), and exposing said film to radiation from the x-ray machine (Column 4, Lines 25-28).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6, 8-12, 19-21, 24, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent to Dawson (USP# 6,364,529) in view of U.S. Patent Application to Moore et al. (PGPUB# 202/0122535).

With respect to Claim 1, Dawson teaches a film imaging assembly cassette comprising a first section and a second section in the form of film dividers (32), wherein said sections comprise a virtual-water material (Column 3, Lines 64-66) for the purpose of simulating a patient's body (Column 4, Lines 19-23).

Dawson does not teach that at least one lead foil sheet is carried within each of said first section and said second section.

Moore et al. teach a film imaging assembly wherein a first section (52) carries a first thin metal screen (51) and a second section (56) carries a second thin metal screen (58), wherein said screens are composed of lead (Paragraph 21, Lines 4-10), to intercept secondary electron emission with said first metal screen (Paragraph 15, Lines 1-5), and to provide additional electrons for radiographic film exposure with said second metal screen (Paragraph 16, Lines 1-4).

It would be obvious to one of ordinary skill in the art at the time of the invention to use the lead screens of Moore et al. in the assembly of Dawson to provide enhanced image sharpness and intensity in a lightweight, easy-to-handle imaging assembly, as taught by Moore et al. (Paragraphs 15-16, and 28).

With respect to Claim 2, Dawson further teaches that said first section and said second section are generally prismatically shaped, with polygonal cross-sections and bounded by parallelograms (32).

With respect to Claim 3, Dawson does not teach first section and second section are fabricated of a plastic material.

Moore et al. teach said first section (52) and said second section (56) are made from conventional support materials, including polymer films and transparent polyesters (Paragraph 92).

It would be obvious to one of ordinary skill in the art at the time of the invention to use the polymeric materials of Moore et al. in the assembly of Dawson, to obtain transparent, flexible, and durable support for said sections, as taught by Moore et al. (Paragraphs 92-93, 105, 108, and 113-114).

With respect to Claim 4, Dawson further teaches said first and second sections are made of a virtual water material (Column 3, Lines 64-66) for the purpose of simulating a patient's body (Column 4, Lines 19-23), but does not teach that said material is a plastic.

Moore et al. teach said first section (52) and said second section (56) are made from conventional support materials, including a large range of polymer films and transparent polyesters (Paragraphs 92, 105, and 107-108).

It would be obvious to one of ordinary skill in the art at the time of the invention to use the polymeric materials of Moore et al. in the assembly of Dawson, to obtain transparent, flexible, and durable support for said sections, as taught by Moore et al. (Paragraphs 92-93, 105, 108, and 113-114).

With respect to Claim 5, Dawson further teaches a sheet of film inserted and retained between said first and second sections (32, and Abstract).

With respect to Claim 6, Dawson, as modified by Moore et al. for Claim 1 above, discloses the claimed invention except for a spacing of approximately 6mm between lead foil sheets in each section and the sheet of film. It would have been obvious to one having ordinary skill in the art at the time the invention was made to set this optimal distance value between said foils and said sheet of film, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).* Furthermore, the applicant has not placed any criticality on spacings larger than 6 mm and has not indicated that any long-standing problem in the art is solved by limiting the spacing between foils and film sheet to approximately 6 mm on either side of said film.

With respect to Claim 8, Dawson teaches a medical phantom (Abstract, Line 1) comprising a film imaging assembly cassette comprising a first section and a second section in the form of film dividers (32), wherein said sections comprise a virtual-water material (Column 3, Lines 64-66) for the purpose of simulating a patient's body (Column 4, Lines 19-23), said sections having outer surfaces facing holder panels (24 and 28), film (Column 5, Lines 8-12), with at least one slab (24) of virtual water (Column 3, Lines 64-66) tissue-equivalent material (Column 4, Lines 20-23) and one slab (74) of lung tissue-equivalent material (Column 4, Lines 1-2) positioned proximate said outer surface side of said first section, and at least one slab (24) of virtual water tissue-equivalent material (Column 3 Lines 64-66, and Column 4 Lines 20-23) positioned proximate said outer surface side of said second section (Figure 2).

Dawson does not teach that at least one lead foil sheet is carried within each of said first section and said second section.

Moore et al. teach a film imaging assembly wherein a first section (52) carries a first thin metal screen (51) and a second section (56) carries a second thin metal screen (58), wherein said screens are composed of lead (Paragraph 21, Lines 4-10), to intercept secondary electron emission with said first metal screen (Paragraph 15, Lines 1-5), and to provide additional electrons for radiographic film exposure with said second metal screen (Paragraph 16, Lines 1-4).

It would be obvious to one of ordinary skill in the art at the time of the invention to use the lead screens of Moore et al. in the assembly of Dawson to provide enhanced image sharpness and intensity in a lightweight, easy-to-handle imaging assembly, as taught by Moore et al. (Paragraphs 15-16, and 28).

With respect to Claim 9, Dawson further teaches said first and second sections are made of a virtual water material (Column 3, Lines 64-66) for the purpose of simulating a patient's body (Column 4, Lines 19-23), but does not teach that said material is a plastic.

Moore et al. teach said first section (52) and said second section (56) are made from conventional support materials, including polymer films and transparent polyesters (Paragraph 92, 105, 108, and 113-114).

It would be obvious to one of ordinary skill in the art at the time of the invention to use the polymeric materials of Moore et al. in the assembly of Dawson, to obtain

transparent, flexible, and durable support for said sections, as taught by Moore et al. (Paragraphs 92-93, 105, 108, and 113-114).

With respect to Claim 10, Dawson teaches a holder for a medical phantom comprising a bottom (12), front (24), back (28), first and second sides (left and right edge sections of 24 and 28), wherein said bottom, front, back, and first and second sides comprise a virtual water material (Column 3, Lines 64-67) for the purpose of simulating a patient's body (Column 4, Lines 19-23).

Dawson does not teach that said virtual water material is a plastic.

Moore et al. teach said first section (52) and said second section (56) are made from conventional support materials, including polymer films and transparent polyesters (Paragraph 92, 105, 108, and 113-114).

It would be obvious to one of ordinary skill in the art at the time of the invention to use the polymeric materials of Moore et al. in the assembly of Dawson, to obtain transparent, flexible, and durable support for said sections, as taught by Moore et al. (Paragraphs 92-93, 105, 108, and 113-114).

With respect to Claim 11, Dawson further teaches said holder comprises threaded legs (16).

With respect to Claim 12, Dawson further teaches said legs (16) further comprise means for adjusting the length thereof in the form of knobs (20), which are turned to adjust length of said legs (Column 2, Lines 48-52).

With respect to Claim 19, Dawson teaches a method for verifying intensity of radiation beams for patient treatment (Column 1, Lines 34-36), said method comprising

obtaining a phantom for mimicking human tissue (Column 1, Lines 27-32, and 34-36), wherein said phantom has a generally flat surface (Figure 2), and wherein said phantom comprises a film imaging assembly cassette (10), comprising a first section and a second section in the form of film dividers (32), wherein said sections comprise a virtual-water material (Column 3, Lines 64-66) for the purpose of simulating a patient's body (Column 4, Lines 19-23), said sections having outer surfaces facing holder panels (24 and 28), film (Column 5, Lines 8-12), with at least one slab (24) of virtual water (Column 3, Lines 64-66) tissue-equivalent material (Column 4, Lines 20-23) and one slab (74) of lung tissue-equivalent material (Column 4, Lines 1-2) positioned proximate said outer surface side of said first section, and at least one slab (24) of virtual water tissue-equivalent material (Column 3 Lines 64-66, and Column 4 Lines 20-23) positioned proximate said outer surface side of said second section (Figure 2), planning system computationally simulating the dose of radiation delivered for patient treatment and to phantom (Column 4, Lines 17-20), calculating dose distributions at specific depths below surface of said phantom for each beam component (Column 4 Lines 22-30, and Column 3 Lines 34-58), setting up radiation beams for actual delivery on said phantom and delivering actual radiation beams intended for treatment onto said phantom (Column 4, Lines 19-30), wherein said phantom houses radiochromic film (Column 4, Lines 60-62), said film generating images for dose distribution measurement as is well known in the art, and comparing actual measurements from film with calculated dose distributions from planning system (Column 4 Lines 30-33, Column 1 Lines 60-67, and Column 2 Lines 1-6).

Dawson does not teach that at least one lead foil sheet is carried within each of said first section and said second section.

Moore et al. teach a film imaging assembly wherein a first section (52) carries a first thin metal screen (51) and a second section (56) carries a second thin metal screen (58), wherein said screens are composed of lead (Paragraph 21, Lines 4-10), to intercept secondary electron emission with said first metal screen (Paragraph 15, Lines 1-5), and to provide additional electrons for radiographic film exposure with said second metal screen (Paragraph 16, Lines 1-4).

It would be obvious to one of ordinary skill in the art at the time of the invention to use the lead screens of Moore et al. in the assembly of Dawson to provide enhanced image sharpness and intensity in a lightweight, easy-to-handle imaging assembly, as taught by Moore et al. (Paragraphs 15-16, and 28).

With respect to Claim 20, Dawson further teaches said phantom is contained within a cassette assembly (10). (Examiner notes that Moore et al. also teach a cassette in Paragraph 9, Lines 6-7.)

With respect to Claim 21, Dawson further teaches determining if differences between said actual dose distributions and said calculated dose distributions are within acceptable levels (Column 1 Lines 26-36, 60-67, and Column 2 Lines 1-6).

With respect to Claim 24, Dawson teaches a method for verifying intensity of radiation beams for patient treatment (Column 1, Lines 34-36), said method comprising obtaining a phantom for mimicking human tissue (Column 1, Lines 27-32, and 34-36), wherein said phantom has a generally flat surface (Figure 2), planning system

computationally simulating the dose of radiation delivered for patient treatment and to phantom (Column 4, Lines 17-20), calculating dose distributions at specific depths below surface of said phantom for each beam component (Column 4 Lines 22-30, and Column 3 Lines 34-58), setting up radiation beams for actual delivery on said phantom and delivering actual radiation beams intended for treatment onto said phantom (Column 4, Lines 19-30), wherein said phantom houses radiochromic film (Column 4, Lines 60-62), said film generating images for dose distribution measurement as is well known in the art, and comparing actual measurements from film with calculated dose distributions from planning system (Column 4 Lines 30-33, Column 1 Lines 60-67, and Column 2 Lines 1-6).

Dawson does not teach said phantom comprises at least one high atomic number powder and at least one tissue-equivalent plastic compound.

Moore et al. teach a phantom imaging assembly wherein said assembly comprises a fluorescent layer containing a high atomic-number powder of calcium tungstate niobium ($CaWO_4$) for higher emission efficiency (Paragraph 94, Lines 8-15), and a tissue-equivalent plastic compound (Paragraph 134).

It would be obvious to one of ordinary skill in the art at the time of the invention to use the materials of Moore et al. in the method of Dawson to the image intensity and resolution on the radiographic film without the need for heavier metal sheets, as taught by Moore et al. (Paragraphs 17-19, and 66-68).

Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application to Moore et al. (PGPUB# 202/0122535) in view of U.S. Patent to Arnold (USP# 5,335,260).

With respect to Claim 16, Moore et al. teach the elements of Claim 13 as disclosed above, but do not teach said high atomic number powder concentration comprises approximately 6% by weight.

Arnold teaches heavy magnesium oxide, a known, insoluble, measurable component of human tissue (especially breast tissue), as a component of the tissue equivalent plastic compound comprising approximately 6% by weight (Column 5, Lines 51-59).

It would be obvious to one of ordinary skill in the art to use the powder of Arnold in the phantom of Moore et al. to provide a phantom material that accurately mimics human tissue x-ray absorption and attenuation properties, as taught by Arnold (Column 5, Lines 24-27).

With respect to Claim 17, Moore et al. teach the elements of Claim 13 as disclosed above, but do not teach said tissue-equivalent plastic compound comprises approximately 94% by weight.

Arnold teaches low-density polyethylene as a component of the tissue equivalent plastic compound comprising approximately 94% by weight (Column 5, Lines 51-59).

It would be obvious to one of ordinary skill in the art to use the polyethylene plastic material of Arnold in the phantom of Moore et al. to provide a phantom material

that accurately mimics human tissue x-ray absorption and attenuation properties, as taught by Arnold (Column 5, Lines 24-27).

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application to Moore et al. (PGPUB# 202/0122535) in view of U.S. Patent to Barthe et al. (USP# 5,569,699).

With respect to Claim 18, Moore et al. teach the elements of Claim 13 as disclosed above, but do not teach said phantom comprises approximately 80.5% carbon by weight and approximately 13.5% hydrogen by weight.

Barthe et al. teach a tissue-equivalent material comprising approximately 80.5% carbon and approximately 13.5% hydrogen by weight, in a polymer that has high resistivity to over come inhomogeneities of electrical fields used in radiation counters (Column 2, Lines 27-32 and 40-53).

It would be obvious to one of ordinary skill in the art to use the polymer material of Barthe et al. in the phantom of Moore et al. to provide a phantom material that accurately mimics human tissue x-ray absorption and attenuation properties, with high resistivity to overcome inhomogeneities of biological equivalent radiation counters (dosimeters) as taught by Barthe et al. (Column 2, Lines 4-39).

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dawson and Moore et al. as applied to claim 1 above, and further in view of U.S. Patent to Nilsson et al. (USP# 6,712,508).

With respect to Claim 7, Moore et al. do not teach said first section and said second section are hingeably related.

Nilsson et al. teach a tissue equivalent phantom (Column 3, Lines 34-40) containing film (13, and Column 4 Line 11) between a first and second section of tissue equivalent material (5, and Column 3 Lines 46-52), wherein said sections are hingeably related at the point where film is inserted between said sections (11, and Column 3 Lines 58-61).

It would be obvious to one of ordinary skill in the art to use the hingeably related sections of Nilsson et al. in the film image assembly of Moore et al. to allow ease of inserting and removing film to re-use phantom.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patents to: Files (USP# 23,179), Sugiyama et al. (USP# 3,753,714), Duden (USP# 3,941,246), Vogl et al. (USP# 4,126,789), Bardoux et al. (USP#4,538,071), Schaffer (USP# 4,546,251), Malamud et al. (USP# 4,788,707), Ridge (USP# 4,794,631), Lanza et al. (USP# 4,956,859), Patel et al. (USP# 5,420,000), Goodenough

et al. (USP# 5,506,884), Aufrichtig et al. (USP# 5,841,835), Mishizawa et al. (USP# 6,594,336), and Dickerson et al. (USP# 6,794,106).

U.S. Patent Application Publications to: Robar et al. (PGPUB# 2001/0033682), Adnani et al. (PGPUB# 2003/0155530), Paliwal et al. (PGPUB# 2003/0231740), and Lang et al. (PGPUB# 2005/0078802).

And the following Non-Patent Documents:

Anderson, D.W., et al., "Comparison of Film and Ion Chamber Systems for Depth-Dose Measurements for a 25 MV Beam." (9 August 1978) Physical Medical Biology, Vol. 24, No. 3, Pp. 636-638.

Hartley, L.D., et al., "Estimating mean glandular dose using proprietary mammography phantoms." (1999) Applied Radiation and Isotopes, Vol. 50, Pp. 205-213.

Lindberg, J.S., et al., "Magnesium bioavailability from magnesium citrate and magnesium oxide." (1990) Journal of the American College of Nutrition, Vol. 9, Issue 1, Pp. 48-55.

Siddle, D., et al., "Calibration of strontium-90 eye applicator using a strontium external beam standard." (1999) Physical Medical Biology, Vol. 44, Pp. 1597-1608.

Yip, W.M., et al., "ROC curve analysis of lesion detectability on phantoms: comparison of digital spot mammography with conventional spot mammography." (2001) British Journal of Radiology, Volume 74, Pp. 621-628.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anastasia Midkiff whose telephone number is 571-272-5053. The examiner can normally be reached on M-F 7-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Edward Glick can be reached on 571-272-2490. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ASM
11/29/05

EDWARD J. GLICK
SUPERVISORY PATENT EXAMINER

12/2/05